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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/848,448 | 05/03/2001 | Ismat Ullah | TNIA CIP | 3068 |

7590 01/24/2003
Bristol -Myers Squibb Company
Patent Department
P.O. Box 5100
Wallingford, CT 06492-7660

EXAMINER

TRAN, SUSAN T

| | |
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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,448

Applicant(s)

ULLAH ET AL.

Examiner

Susan Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-24 and 27-53 is/are pending in the application.
- 4a) Of the above claim(s) 32-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-24, 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Terminal Disclaimer and Amendment filed 10/29/02.

Terminal Disclaimer

The terminal disclaimer filed on 10/29/02 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US 6,331,316 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-24, 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. WO 94/03160, in view of Howard et al. US 5,049,394, and Bogardus et al. US 6,207,650.

Morella teaches pelletized composition comprising core including 0.1 to 95% active ingredient, 0.1 to 55% binding agent, filler, carrier, excipients, and glidants (see abstract, and pages 6-7). The active ingredient can be erythromycin (page 4). The

core is further being coated with 3 to 50% polymer, 0 to 50% plasticizer (pages 8-9, and formulations 1-7).

Howard teaches high drug load pharmaceutical composition comprising from about 80% to about 96% of drug, *e.g.*, erythromycin; from about 1% to about 12% binder-plasticizer, such as, hydrophilic polymers; 0.5% to about 12% of starch-based excipient, such as, sodium starch glycolate, pregelatinized starch, or polyvinylpyrrolidone; and from about 0.2 to about 5% water-soluble binder, *e.g.*, hydroxypropylmethyl cellulose (columns 2-4). The composition is in spheronizer to form beads that may be coated with film former and plasticizer, and the coated beads can be filled into hard shell capsules (columns 4-5).

Howard and Morella are silent as to the teaching of 2',3'-dideoxyinosine as active agent.

Bogardus teaches pharmaceutical composition comprising antiviral drug, *e.g.*, 2',3'-dideoxyinosine in the form of powders, granules that can be enteric coated (columns 4-5). Accordingly, it would have been *prima facie* obvious for one of ordinary skill in the art to prepare the composition of Morella and Howard using 2',3'-dideoxyinosine as active ingredient in view of the teaching of Bogardus because the references teach the advantageous result of acid labile drug in oral dosage form.

Response to Arguments

Applicant's arguments filed 10/29/02 have been fully considered but they are not persuasive.

Applicant argues that neither Morella nor Howard teaches the specific active agent, such as 2',3'-dideoxyinosine in an amount of at least 80%. Contrary to the applicant's argument, both Morella and Howard teaches the use of acid labile drugs in an amount of at least 80% or from 0.1-95%. In response to applicant's arguments against the references individually (regarding to the specific active agent), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the references were rejected in combination with Bogardus et al. Bogardus et al. is relied upon solely for the teaching of acid labile drug, such as 2',3'-dideoxyinosine.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600